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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,081	10/14/2003	Martin R. Hodge	004974.01148	5030

22907 7590 06/13/2007

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,081	HODGE, MARTIN R.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,20 and 28* is/are rejected.

7)☒ Claim(s) *13-19,21-27 and 29-36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/2007 has been entered.

Applicant's amendment of claims 1, 7 and 9 and the addition of new claims 13-36, in the paper of 4/2/2007, is acknowledged. Claims 1-36 are at issue and are present for examination.

Applicants' arguments filed on 4/2/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 16-36 are objected to because of the following informalities:

Claims 16-19, 21-27, 29-36 are objected to because they depend from rejected claims 1, 7 or 9.

Claims 20 and 28 recite "comprises the fusion protein..." There is no antecedent basis for "the fusion protein" and the referenced SEQ ID NO: 1 does not encode a "fusion protein".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 20 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 1-12. In response to this rejection applicants have amended claims 1, 7 and 9 and added new claims 13-36 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection together with the below rejection based upon a lack of scope of enablement on the basis that claims 1, 7 and 9 have been amended to delete the recitation of "a nucleotide sequence which is at least 97% identical...: and

that claims 1-12 as amended now recite only polypeptides that are explicitly disclosed in the specification.

Applicants complete amendment and argument is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously made of record and repeated herein.

It continues to be noted that the rejected claims are drawn to methods of identifying a compound which binds to a 14189 polypeptide having kinase activity and that applicants previous amendment does not require that the polypeptides used have kinase activity, but that they merely have some homology to SEQ ID NO: 1.

It continues that applicants have only described minimal species of the claimed genus and applicant's claims, as amended require no structure to function relationship for the polypeptides used in the claimed method.

Given this lack of additional representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention. Applicants claims now read on any method for identifying a compound which binds to a 14189 polypeptide comprising contacting any 14189 polypeptide which is encoded by a nucleic acid sequence comprising the nucleotide sequence of SEQ ID NO: 1, nucleotides 48-1682 of SEQ ID NO: 1, or the cDNA insert of the plasmid deposited with ATCC as Accession Number PTA-2333. the currently amended claims continue to read on polypeptide fragments of the above referenced sequences which have no specific activity associated with them. It

continues that such a broad genus of claims has not been sufficiently described by applicants.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-12, 20 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those methods for identifying compounds which bind to a 14189 polypeptide which involve the use of the polypeptide having the complete amino acid sequence of SEQ ID NO: 2 and having kinase activity, does not reasonably provide enablement for all methods for identifying a compound which bind to any polypeptide, comprising contacting the polypeptide with or without a target molecule with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is merely encoded by any nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1-12. In response to this rejection applicants have amended claims 1, 7 and 9 and added new claims 13-36 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection together with the above rejection based upon a lack of written description on the basis that claims 1, 7 and 9 have been amended to delete the recitation of "a nucleotide sequence which is at least 97% identical...: and that claims 1-12 as amended now recite only polypeptides that are explicitly disclosed in the specification.

As above, applicants complete amendment and argument is acknowledged and has been carefully considered, however, is not found persuasive for the reasons previously made of record and repeated herein.

It continues to be noted that the rejected claims are drawn to methods of identifying a compound which binds to a 14189 polypeptide having kinase activity and that applicants previous amendment does not require that the polypeptides used have kinase activity, but that they merely have some homology to SEQ ID NO: 1.

It continues that applicants have only enabled those minimal species of the claimed genus and applicant's claims, as amended require no structure to function relationship for the polypeptides used in the claimed method.

Given this lack of additional representative species as encompassed by the claims, applicants not enabled the scope of the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention. Applicants claims now read on any method for identifying a compound which binds to a 14189 polypeptide comprising contacting any 14189 polypeptide which is encoded by a nucleic acid sequence comprising the nucleotide sequence of SEQ ID NO: 1, nucleotides 48-1682 of SEQ ID NO: 1, or the

cDNA insert of the plasmid deposited with ATCC as Accession Number PTA-2333. the currently amended claims continue to read on polypeptide fragments of the above referenced sequences which have no specific activity associated with them. It continues that such a broad genus of claims is not sufficiently enabled.

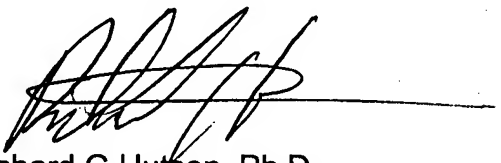
Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all methods for identifying a compound which binds to any polypeptide, comprising contacting the polypeptide with or without a target molecule, with a test compound and determining whether the polypeptide binds to the test compound, wherein the polypeptide is merely encoded by any nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those methods having the necessary steps and the desired results is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
6/10/2007